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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
1141 Central Parkway
Cincinnati, OH 45202

July 11, 1997

WARNING LETTER
CIN-WL-97-457

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Walter E. Kalberer, President
WEK Industries, Inc.
1085 Jefferson Street
Jefferson, OH 44047

Dear Mr. Kalberer:

The Food and Drug Administration (FDA) conducted an inspection on June 16-19, 1997, of your firm that contract manufactures sharps containers for [redacted]. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing and storage are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The following deviations from Device GMP's were documented:

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures.
- Failure to have established written procedures for acceptance of the plastic component, [redacted], and to conduct acceptance testing.
- Failure to record the lot number, wall thickness result and shift on the finished product inspection sheet.
- The finished product inspection sheet showed that sharps containers are produced that do not meet the customer's minimum weight standard. There was no documentation of corrective action that might have been taken.
- Failure to establish and implement reprocessing procedures.
- Failure to establish written procedures for the calibration of measurement equipment such as the calipers and scale.

- Documentation of the [redacted] Blow Mold Machine does not indicate that routine maintenance is performed in accordance with the established maintenance schedule.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office within fifteen (15) days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, Compliance Branch, 1141 Central Parkway, Cincinnati, Ohio, 45202.

We acknowledge receipt of an undated letter from Murrel Godfrey, Manager, QC/QA which covers planned corrections made as a follow-up to the Inspectional Observations. You may want to provide copies of your new procedures in response to this letter.

Sincerely,

for John R. Marzilli
District Director
Cincinnati District

LEB/pjk